Appendix A

United States Court of Appeals

For the Second Circuit

No. 325—September Term, 1965

(Argued February 25, 1966. Decided April 13, 1966)

Docket No. 30261

The Toilet Goods Association, Inc.; Anita D'Foged, Inc.; Avon Products, Inc.; Beauty Counselors, Inc.; Bonne Bell, Inc.; Bourjois, Inc.; Charles of the Ritz, Inc.; Chesebrough-Pond's, Inc.; Christian Dior Perfumes Corp.; Clairol Incorporated; Colonial Dames Co., Ltd.; Coty, Inc.; Faberge Inc.; Frances Denny, Inc.; The Fuller Brush Co.; The George W. Luft Co., Inc.; The Gillette Company; A. M. Hansen, doing business as House of Hollywood; Harper Method, Inc.; Helena Rubinstein, Inc.; Helene Curtis Industries, Inc.; Henry/Haran/Hutchings, Inc.; Herbold Laboratory, Inc.; John H. Breck, Inc.; Kolmar Laboratories, Inc.; Lady Lennox Company, Inc.; Lehn & Fink Products Corporation; Arnold L. Lewis, doing business as Studio Cosmetic Co.; Max Factor & Co.; Maybelline Co.; Merle Norman Cosmetics, Inc.; Jack B. Nethercutt, doing business as Nethercutt Laboratories; Neutrogena Corp.; Nutrilite Products,

INC.; OLD 97 COMPANY; PRIVATE LABEL COSMETICS CO., INC.; PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORATORIES, INC.; SHULTON, INC.; AND YARDLEY OF LONDON, INC., PLAINTIFFS-APPELLEES

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS-APPELLANTS

Before WATERMAN, MOORE and FRIENDLY, *Circuit Judges*

APPEAL BY THE SECRETARY OF HEALTH, EDUCATION AND WELFARE AND THE COMMISSIONER OF FOOD AND DRUGS FROM AN ORDER OF THE DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK, HAROLD R. TYLER, JR., JUDGE, DENYING THEIR MOTION TO DISMISS OR GRANT SUMMARY JUDGMENT IN AN ACTION FOR A DECLARATION OF INVALIDITY OF FOUR FOOD AND DRUG ADMINISTRATION REGULATIONS RELATING TO COLOR ADDITIVES. AFFIRMED AS TO COUNTS 1, 2 AND 3; REVERSED AS TO COUNT 4.

ARTHUR S. OLICK (ROBERT M. MORGENTHAU, UNITED STATES ATTORNEY FOR THE SOUTHERN DISTRICT OF NEW YORK; JAMES G. GREILSHEIMER, ASSISTANT UNITED STATES ATTORNEY, OF COUNSEL), FOR DEFENDANTS-APPELLANTS

EDWARD J. ROSS (BREED, ABBOTT & MORGAN, NEW YORK, N.Y.; STEPHEN R. LANG, OF COUNSEL), FOR PLAINTIFFS-APPELLEES

FRIENDLY, *Circuit Judge.*

In July 1960, Congress added to the Federal Food, Drug, and Cosmetic Act a number of new provisions known as the Color Additive Amendments, 74 Stat. 397, 21 U.S.C. §§ 321–376. These were intended

> "to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerance, under which such additives may be safely used." H. R. Rep. No. 1761, 86th Cong., 2d Sess., 1960 U.S. Code Cong. & Ad. News 2887.

The Commissioner of Food and Drugs, to whom the Secretary of Health, Education and Welfare has delegated the Department's functions under the Act, 22 F. R. 1051 (1957), 25 F. R. 8625 (1960), held rule-making proceedings conforming to § 4 of the Administrative Procedure Act, 5 U.S.C. § 1003, and issued Color Additive Regulations, 21 C. F. R. Part 8, effective, with certain exceptions, on June 22, 1963.

The following November the Toilet Goods Association, a trade organization of cosmetic manufacturers whose members allegedly represent 90% of annual United States sales, and forty manufacturers and distributors of cosmetics brought this action against the Secretary and the Commissioner in the District Court for the Southern District of New York for a declaratory judgment that four provisions of the Regulations exceeded the authority conferred by the statute. Jurisdiction was properly predicated on 28 U.S.C. §§ 1331 and 1337. See *Smith* v. *Kansas City Title & Trust Co.*, 255 U.S. 180 (1921).[1] The defend-

[1] We thus do not reach the question whether § 10 of the Administrative Procedure Act, 5 U.S.C. § 1009, constitutes an affirmative grant of jurisdiction with respect to the review of federal administrative action, as the Supreme Court apparently assumed in *Rusk* v. *Cort*, 369 U.S. 367, 371–72 (1962) and we recently did in *Cappadora* v. *Celebrezze*, —— F. 2d —— (2 Cir. 1966). But see *Ove Gustavsson Contracting Co.* v. *Floete*, 278 F. 2d 912 (2 Cir.), cert. denied, 364 U.S. 894 (1960). Since 28 U.S.C. §§ 1336–40 do not require a jurisdictional amount, this question arises only in cases such as social security,

ants moved to dismiss or to strike certain portions of the complaint on various grounds, among others that the case was inappropriate for declaratory relief and that the action was an unconsented suit against the sovereign; plaintiffs cross-moved for summary judgment. In November 1964 Judge Tyler denied both motions in an opinion, 235 F. Supp. 648, relying in part on *Abbott Labs* v. *Celebrezze,* 228 F. Supp. 855 (D. Del. 1964), where the court had granted a declaratory judgment invalidating labeling regulations under the same statute. A year later, when the case was nearly ready for trial, the Secretary and the Commissioner renewed their motion to dismiss on the two grounds stated, arguing that a different conclusion on "the issue of justiciability" was called for by the Third Circuit's reversal of the *Abbott Laboratories* decision, 352 F. 2d 286 (1965),[2] and the District of Columbia Circuit's recent holding that declaratory relief was not available to challenge certain regulations adopted under the Tobacco Inspection Act, 7 U.S.C. § 714(b), *Danville Tobacco Ass'n* v. *Freeman,* 351 F. 2d 832 (D.C. Cir. 1965). Judge Tyler adhered to his determination but, at the defendants' request, made the necessary certification for an application to prosecute an interlocutory appeal under 28 U.S.C. § 1292(b); permission to appeal was granted by a panel of this court.

The first two counts of the complaint charge that the Regulations exceed the authority conferred by the statute in treating finished cosmetic products and all diluents—unpigmented materials with which colors are mixed—as "color additives" subject to various re-

passport and citizenship matters, where none of these sections is applicable and the jurisdictional amount required by § 1331 is not met.

[2] Subsequent to the argument of this appeal, certiorari was granted, 34 U.S.L. Week 3294 (March 1, 1966) (No. 824).

quirements for testing and administrative certification. The basic section of the Color Additive Amendments is § 706 of the Act, 21 U.S.C. § 376, which provides that a "color additive" shall be deemed unsafe unless it meets two conditions:[3] The additive must be covered by a "regulation," issued by the Secretary on a finding of suitability, which lists it for use either generally or under prescribed conditions; and it must either come from a batch certified for such use by the Secretary under appropriate regulations or have been exempted from the certification requirement.

The term "color additive," on which the controversy turns, is defined in § 201(t)(1), as a material which

> (A) is a dye, pigment, or other substance made by a process of synthesis * * * or otherwise derived * * * from a vegetable, animal, mineral, or other source, and
>
> (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto.

21 U.S.C. § 321(t)(1)

The Regulations of the Food and Drug Administration (FDA) interpret the statutory definition of color additive as including "all diluents" and state further that

> A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." Reg. § 8.1(f).

[3] This is subject to an exception, not here important, for color additives covered by an exemption for investigational use by qualified experts, 21 U.S.C. §§ 376 (a)(2) and (f).

The term "diluent" is defined as:

> any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.
>
> Reg. § 8.1(m)

The manufacturers admit that the coloring ingredient in a cosmetic is a "color additive" fully subject to both listing and certification requirements of § 706, and that a "diluent," in what they insist is the accepted definition of an inert substance used to dilute dyes and pigments, is subject to the Secretary's power to certify additives "with safe diluents or without diluents," § 706(c). They complain, however, that the Regulations' comprehensive definition of "color additive" goes beyond the reach of the statute in imposing both listing and certification requirements on finished products—like lipstick, nail polish, etc.—and non-color ingredients that were never intended to be subject to premarketing clearance, and on traditional diluents that were meant to be subject only to certification as components of dyes and pigments.

The third count of the complaint relates to provisions in the Regulations which attempt to subject hair dye products to premarketing clearance in what is alleged to be violation of the exemption recognized in the statute. The Act as passed in 1938, in defining

those cosmetics that were deemed to be adulterated, contained in § 601(a) an explicit exemption for hair dyes:

> This provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so many cause blindness.", and the labeling of which bears adequate directions for such preliminary testing.
>
> 52 Stat. 1054

The exemption was carried forward in § 601(e) which declared that a cosmetic should be deemed adulterated "If it is not a hair dye and it bears or contains a coal-tar color other than one" from a certified batch. When Congress revised the statute in the 1960 Amendments, it left § 601(a) as it was but modified § 601(e) to read "If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe" within the meaning of § 706.

The Regulations recognized the statutory exemption where proper labeling called for use of the patch test but, armed with an expansive definition of "color additive" in § 8.1(f) which would on its face seem to include in a preparation for use on the hair any coloring ingredient as well as the finished product, proceeded to limit the exemption as follows:

> The "hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives

with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious substance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.

Reg. § 8(u)

The manufacturers claim that the Regulations go beyond the statute in several ways: Whereas the 1938 Act literally exempted from premarketing clearance any coal-tar hair dye complying with the statutory condition of notice and the amendments did not purport to effect any change, the Regulations grant exemption only if the color additive in the hair dye substance is one whose irritating qualities would be detected by a patch test; and, contrary to the longstanding interpretation—in effect by regulation when the amendments were adopted[4]—which applied the exemption in its full scope to dual-purpose hair products like shampoos, rinses and tints with a coal-tar coloring component, the Regulations seem to limit the exemption to the coloring ingredient itself.

[4] Reg. § 1.200 apparently defined the term "coal-tar hair dye" in the § 601(a) exemption to include "all articles containing any coal-tar color." This definition of hair dyes was deleted by the Commissioner as superseded by § 8.1(u) of the Color Additive Regulations. 28 F.R. 10688 (1963).

Count 4 of the complaint attacks a section of the Regulations, § 8.28(a)(4), which states that when it appears to the Commissioner that a person has refused to permit duly authorized employees of the FDA "free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived," he may suspend certification service to such person until adequate corrective action is taken. The first sentence of § 704(a) of the Act, applicable to all goods, drugs, devices, or cosmetics subject thereto, authorizes the Secretary to inspect any "factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labelling therein"; the second sentence, dealing only with places where prescription drugs are manufactured, processed or held, provides for inspection extending "to all things therein (including records, files, papers, processes, controls, and facilities)." The manufacturers say the challenged regulation illegally extends to cosmetics the broadened inspection authorized only for prescription drugs, and improperly subjects trade secrets to exposure.

The expanded definition of "color additives," the narrowing of the hair dye exemption, and the allegedly compelled disclosure of secret formulae and processes impose, the manufacturers claim, burdens not contemplated by the statute and threaten immediate and irreparable injury. Even though coloring ingredients have been properly pretested, listed and certified in compliance with the statutory clearance scheme, the regulations require filing a separate listing application for each finished product, traditional diluent and non-color ingredient, including those formerly exempted under the hair dye provision; each

application must be accompanied by a $2,600 filing fee, Reg. § 8.50(c), and supported by extensive scientific tests establishing suitability for intended use, Reg. § 8.4(c). Even after listing, every ingredient and finished product must come from a certified batch unless the Secretary has granted an exemption; a minimum fee of $100 is charged for each certification, Reg. § 8.51(a). An affidavit by one manufacturer claimed that the listing of its finished products alone for the issuance of regulations would entail filing fees of $7,000,000 and testing costs of nearly $42,000,000, and that certification fees for a single year would amount to $750,000.[6] Beyond such out-of-pocket costs, increased by substantial additional expenses for record-keeping, compliance with the challenged regulations, by requiring significant changes in established business practices and curtailing distribution of new products, allegedly would cause major and costly disruption of the cosmetic industry. Moreover, the disclosure of formulae and processes necessary to meet the new listing requirements and to avoid loss of certification for refusing inspection allegedly would result in misappropriation of trade secrets and discourage research and development of improved cosmetic products.

Failure to comply with the challenged regulations could have serious consequences if they are valid. Under § 601 of the Act, a cosmetic other than a hair dye is deemed adulterated if "it is, or it bears or contains, a color additive which is unsafe" within the meaning of § 706(a). Projection of any adulterated

[6] Very likely these figures are exaggerated since they take no account either of the FDA's power to require information on diluents as a condition of approving coloring ingredients and granting certification or of the likelihood of exemption from certification.

article into the stream of interstate commerce and refusal to allow inspection required by § 704 are prohibited acts under the statute, and are subject to injunction and entail criminal liability, §§ 301–303; and any adulterated article may be seized under § 304. The manufacturers say that, apart from all else, the publicity incident to criminal or civil proceedings against them for failure to comply with the Regulations would be seriously detrimental in a highly competitive industry which spends millions in cultivating public good will and is dependent on consumer confidence in the integrity of its products.

The Secretary and the Commissioner respond that the fears as to the dilemma posed by the Regulations are exaggerated. They insist that the Regulations merely expound the manner in which they intend to construe the amendments, that nothing has yet been done to apply the provisions of which plaintiffs complain, and that ample opportunity to test the Regulations in concrete fact situations is afforded by the path for review spelled out in the statute. If the manufacturers will only comply with the listing and certification requirements, the FDA's application of the statute will, under § 706(d), be subject to the general administrative provisions on hearings and review in § 701. Since the review authorized in § 706(d) is directed at decisions approving or disapproving listing and certification and §§ 701 (e) and (f) are limited to review of other specifically enumerated agency determinations, the contention is not that the statutory provisions afford a direct path to review of the general regulations on listing requirements; it is rather that they furnish an indirect but nevertheless sufficient one which the manufacturers ought to have taken. The proper course, defendants say, is for a manufacturer to petition for the listing of dilu-

ents and finished cosmetic products as color additives, while protesting against the need for doing so and conforming with the detailed requirements for filing information only to the extent he believes proper under the statute; such a petition could be accompanied by a request for exemption from batch certification, again with appropriate protest and non-compliance with the requirement of factual data to support the application. Either the FDA would retreat from applying its announced interpretation of the statute and grant the petition and the request for exemption, or it would deny them, in which event the road to a court of appeals would be open under §§ 701 (e) and (f).

II

The serious questions* are whether direct challenge of the Regulations by suit in a district court is impliedly barred by the availability of review of listing and certification denials in a court of appeals, and whether the controversy is appropriate for judicial determination prior to application of the Regulations in a particular factual situation.

We are not persuaded that by providing a procedure for review of certain administrative decisions under the Food and Drug Act in the courts of appeals, Congress meant to foreclose relief with respect to

*We need not discuss in the text the surprising contention that an action for a declaration that federal regulatory officers have acted in excess of their authority constitutes an unconsented suit against the United States. The contrary is clearly established by *Philadelphia Co.* v. *Stimson*, 223 U.S. 605, 619–20 (1912), see *Stark* v. *Wickard*, 321 U.S. 288, 299 (1944), and indeed follows inevitably from *Ex parte Young*, 209 US. 123 (1908); law officers of the Government ought not to take the time of busy judges or of opposing parties by advancing an argument so plainly foreclosed by Supreme Court decisions.

other agency action under the Administrative Procedure Act § 10, 5 U.S.C. § 1009, or the Declaratory Judgement Act, 28 U.S.C. § 2201, in a case where this would otherwise be appropriate. The agency determinations specifically reviewable under § 701(e) relate to such technical subjects as chemical properties of particular products and the formulation and application of safety standards for protecting public health; Congress naturally did not wish courts to consider such matters without the benefit of the agency's views after an evidentiary hearing before it. Section 701, however, also contemplated other less specialized administrative action by authorizing, in subsection (a), the making of regulations for the efficient enforcement of the statute, and it expressly declared in subsection (f) that the provision for review of certain orders in the courts of appeals was "in addition to and not in substitution for any other remedies provided by law." 21 U.S.C. § 371(f)(6). The section as a whole does not indicate to us any congressional intent either to insulate administrative action not covered by subsection (e) from challenge as in excess of statutory authority, see *Stark* v. *Wickard*, 321 U.S. 288, 308–11 (1944); cf. *Cappadora* v. *Celebrezze*, 356 F. 2d 1, 5 (2 Cir. 1966), or to postpone immediate challenge to such action where awaiting the issuance of adjudicative orders subject to statutory review would provide less effective relief.[1] Insofar as *Abbott Labs.* v. *Cele-*

[1] The legislative history of the 1938 Act suggests that Congress had no intention of limiting review of other action by adopting a special procedure for the enumerated determinations. The House Report, referring to the savings clause in § 701(f)(6), stated:

> There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the

brezze, 352 F. 2d 286, 289 (3 Cir. 1965), cert. granted, intimates otherwise, we are unwilling to follow it.

The question whether a plaintiff may obtain judicial relief in cases like this has been variously phrased as whether he has "standing" to challenge the administrative action as a person "suffering legal wrong" or "aggrieved" within the meaning of § 10 of the APA, whether the dispute is an "actual controversy" within the Declaratory Judgment Act, or whether it is sufficiently "ripe" for resolution by the courts. See Jaffe, Judicial Control of Administrative Action 395–98 (1965). In fact, the critical issue is apt to be less a matter of standing or of actual controversy than of the advisability of reviewing an administrative rule prior to its application in a specific factual situation. The current healthy trend toward implementing agency policy by rule-making cuts both ways with respect to declaratory relief—increasing the need for this sort of assistance on the part of those subjected to such rules, see *Columbia Broadcasting Sys., Inc.* v. *United States*, 316 U.S. 407, 421 (1942), but also creating a danger that, unless the courts are circumspect, administration may be improperly halted, at least temporarily, before it

---

enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.

H.R. Rep. No. 2139, 75th Cong., 3d Sess., p. 11 (April 14, 1938).

The accompanying minority report, in endorsing the Secretary's challenge to the new review provisions as jeopardizing enforcement of the statute, indicated that the special procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency. H.R. Rep. 2139, Pt. 2 (April 21, 1938).

has gotten the slightest start.[8] The problem is not to be solved, as the parties suggest, by applying some readily procurable litmus paper which will determine whether a controversy is "justiciable"; what is required, as in the case of challenge to the constitutionality of a statute, is a reasoned evaluation of "both the appropriateness of the issues for decision by courts and the hardship of denying judicial relief." *Joint Anti-Fascist Refugee Comm.* v. *McGrath*, 341 U.S. 123, 156 (1951) (*Frankfurter, J.*, concurring); see Jaffe, *supra*, at 396, 423.

The appropriateness of passing judgment on the validity of an administrative regulation prior to its application to particualr facts depends on such factors as how far the rule represents the definitive position of the agency and the extent to which the challenge raises a clearcut legal issue susceptible of judicial solution without reference to fact variables arising in its implementation. Cf. *Northeast Airlines, Inc.* v. *CAB*, 345 F. 2d 662, 664 (1 Cir. 1965). Review might be considered premature where an agency rule had not received substantially as full consideration in its formulation as it would have in subsequent application, or where future experience would be likely to result in significant modifications as to its

[8] The danger of unwarranted postponement of the effectiveness of agency action is augmented by the fact that a suit for declaratory relief must be brought in a district court, twice removed from the supreme tribunal, whereas adjudicative orders are generally reviewable either in courts of appeals or in specially constituted district courts from which appeal lies directly to the supreme court. Yet here too there is another side; a district court may be in a better position than a court of appeals to carry out fact finding, as Congress recognized in the Hobbs Act, 5 U.S.C. § 1037(b).

precision or scope. Judicial determination might also be deemed inappropriate where the controversy over the rule did not present a legal issue that a court was qualified to resolve without reference to factual determinations more effectively made by the agency familiar with day to day administration. See Jaffe, *supra*, at 406. In this case, however, the Regulations under attack were issued after a full hearing with notice and by their terms represent the definitive agency position on the reach of the statutory requirements for listing and certification of cosmetics, see *Columbia Broadcasting Sys., Inc.* v. *United States*, *supra*, 316 U.S. at 422; *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, 198 (1956); to the extent that they purport to apply premarketing requirements to broad categories like finished products and noncoloring ingredients and define the hair-dye exemption, they appear, *prima facie*, to be susceptible of reasoned comparison with the statutory mandate without inquiry into factual issues that ought to be first ventilated before the agency. Indeed, it is manifest that if the manufacturers adhere to their legal position, *pro forma* individual applications to the FDA for listing and certification would produce a record no more, and very likely less, illuminating than what the district court will develop at trial of this action in which the great bulk of the industry is represented and will be bound. The mere fact that the procedure which the defendants suggest would bring the issue directly to a court of appeals without prior resort to a district court, while entitled to some weight, is not controlling. As indicated earlier, the statutory procedure for review of individual determinations in the courts of appeals was not intended as a means for challenging FDA rule-making of the usual sort; as shown by the authorities discussed below, the mere fact that pursuit of that course could

produce a decision on legal issues similar to that here sought does not make its use mandatory.

With respect to the other relevant consideration, the degree of hardship warranting declaratory relief, although some older precedents suggest broadly that an administrative ruling is not reviewable until and unless it imposes an obligation or subjects the plaintiff to some civil or criminal liability, see, e.g., *United States* v. *Los Angeles & Salt Lake R.R.*, 273 U.S. 299, 309–10 (1927); *Shannahan* v. *United States*, 303 U.S. 596, 599 (1938), there has been a growing recognition that the timeliness of review depends on a broader concept of the substantiality of present or immediate harm. See 3 Davis, Administrative Law Treatise § 2107 (1958). In *Columbia Broadcasting Sys., Inc.* v. *United States*, 316 U.S. 407, 417–21 (1942), the Supreme Court declared that though a particular rule does not of itself deny a license or directly impose sanctions, it may nevertheless be reviewable if it establishes a general standard of conduct which by its very promulgation demands conformity and poses, for the plaintiff or others with whom he must deal, the alternatives of compliance or severe penalties of forfeiture or disruption of business operations. In *Frozen Food Express* v. *United States*, 351 U.S. 40, 43–44 (1956), the Court recognized that an agency order generally announcing the scope of administrative regulation was subject to immediate frontal attack, although opportunities for later challenge were sure to come from a cease and desist order by the ICC, see *Eastern Texas Motor Lines* v. *Frozen Food Express*, 351 U.S. 49 (1956), or suit for an injunction by the agency or competitors.* And in *United*

*If it be said that the carrier was subject to liability for criminal penalties even before a cease and desist order or an injunction, the same is true here.

States v. *Storer Broadcasting Co.*, 351 U.S. 192, 199–200 (1956), declaratory rules setting limits on the number of licenses to be granted for broadcasting stations under common ownership were held to be immediately reviewable because they operated "to control the business affairs" of the plaintiff and made it impossible to "cogently plan its present or future operations" so long as their validity remained undetermined; direct challenge to the regulations was permitted even though review might have been obtained by provoking an adverse administrative order, see 351 U.S. at 208 (dissenting opinion).[10] See also *Flemming* v. *Florida Citrus Exch.*, 358 U.S. 153, 168 (1958).

We see little profit in debating the point, much discussed by the parties, whether the Regulations are "interpretative" or "legislative." Although that issue

[10] In fact the FCC dismissed the plaintiff's application for an additional station on the basis of the new rules the very day they were adopted, 351 U.S. at 197, but review of the particular decision was not sought.

We recognize that in *Storer* review of the rule was in the Court of Appeals for the District of Columbia, the same tribunal to which Storer would have gone for review of the denial of an application; but the dissenters thought the rationale of the majority would support a suit for declaratory relief in a district court after the 60-day limitation for seeking review by the Court of Appeals had expired, 351 U.S. at 210 (dissenting opinion of Harlan, *J.*). A more important differentiating consideration may be that awaiting denial of a future application may not have afforded a broadcaster who had reached the ceiling so full an opportunity for challenge as might appear at first blush; if the application was a competitive one for a new license, the FCC might predicate denial on other grounds, and to negotiate a transfer of an existing license in the teeth of the multiple-ownership rules would be of dubious business practicability. However, this ground for distinguishing *Storer* would not apply to *Frozen Food Express*.

would have to be faced if the FDA had failed to comply with the rule-making procedures of § 4 of the APA because of a claim on its part that the Regulations were merely "interpretative," the interpretative character of a regulation does not necessarily make it unripe for review; we perceive no reason why a rule whereby an agency subjects to regulation activities contended to be immune should be exempt from immediate review because it purports to interpret a statute although it would not be if made in the exercise, contended to be illegal, of a substantive rule-making power. See *Frozen Food Express* v. *United States, supra;* Jaffe, Judicial Control of Administrative Action 405–07 (1965); and 1 Davis, Administrative Law Treatise § 5.03 (1965 Pocket Part), criticizing on this ground *American President Lines, Ltd.* v. *FMC,* 316 F. 2d 419 (D.C. Cir. 1963), on which defendants rely. Neither do we think anything is to be gained by an attempt at comprehensive review of the decisions; the many cases in this area are not truly reconcilable and the law has been moving in the direction of greater freedom of review, see Jaffe, *supra,* at 412–17 (which, *inter alia,* criticizes another decision relied on by defendant, *Helco Prods. Co.* v. *McNutt,* 137 F. 2d 681 (D.C. Cir. 1943)), and 3 Davis, Administrative Law Treatise §§ 21.06–21.08 (1958). We limit ourselves to the two recent Court of Appeals decisions which defendants most strongly urge upon us.

Danville Tobacco Ass'n v. *Freeman,* 351 F. 2d 832 (D.C. Cir. 1965), was a rather weak case for declaratory relief. The plaintiffs there were neither threatened with penalties nor, like those in *Frozen Food* and here, faced with the need of applying for licenses to permit continuation of an established business; moreover, there was no showing that the challenged regulation was in fact preventing expansion of their

operations, since they had filed no applications and petitions by other applicants had been denied on grounds other than those attacked. Agreeing with the defendants that *Abbott Labs* v. *Celebrezze*, 352 F. 2d 286 (3 Cir. 1965), cert. granted, is not distinguishable on any satisfying basis, we must confess, with all respect, our inability to understand why the plaintiffs there should be required to violate the challenged FDA regulation in order to raise the same legal issue as to which the district court had granted declaratory relief. Insofar as the *Abbott* decision rested on a negative implication from the limited review provisions of the Food and Drug Act, we have already noted our inability to agree.

III.

In applying the general considerations thus developed to the precise issues here presented, we must bear in mind that this appeal is not from a declaratory judgment but from the denial of a motion to dismiss a complaint seeking one. The issue on such an appeal is not whether the grant of a declaratory judgment was in fact appropriate but whether it so clearly would not be that dismissal *in limine* was required.

As regards the counts of the complaint challenging the inclusion of finished products and color additives and the alleged restrictions of the hair-dye exemption, the appeal must fail. These Regulations appear to have an immediate impact on the industry, posing the unacceptable alternatives of complying or of incurring possible forfeitures and criminal liability, and calling into question long standing practices of premarketing testing and clearance. The issues framed by the counts of the complaint addressed to these Regulations appear sufficiently suitable for immedi-

ate judicial resolution and the threatened harm sufficiently great, that the district court properly declined to dismiss them. If the court should find that the issues are not susceptible of resolution without detailed factual evidence that ought to be first sifted by the agency, or that measures being taken by the FDA for the listing and exemption from certification of approval diluents have so reduced the hardship on the plaintiffs as to make declaratory relief inappropriate, it need not proceed to judgment. But, so far as we can now see, the sooner the industry's claims as to the coverage of the Act in these respects are determined, the better for everybody. As said in Jaffe, Judicial Review of Administrative Action 404 (1965), "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan or not to plan his operation." Moreover, the party disappointed by court decision may wish to take the case to Congress.

The fourth count of the complaint, relating to agency inspection of formulae and processes, stands differently. Here the challenged regulation, §8.28(a)(4), does not of itself demand compliance at the expense of penalties. A manufacturer who refuses access to his trade secrets is not threatened with criminal liability or seizure; the regulation does not suggest that such refusal will be deemed a "prohibited act" under the statute, as it would be in the case of prescription drugs. It simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification. Moreover, the next paragraph §8.29(b), says that upon receipt of notice of suspension, the person so notified may request a hearing upon the factual basis therefor. If after such hearing the Commissioner should adhere to

his refusal to certify, review by a court of appeals would seem available under §§706(d) and 701(f); if not, an action could be brought in the district court.

In this instance the possibility of unlawful injury to the plaintiffs is, on its face, too remote for declaratory relief. No one can now say whether the Commissioner will ever make a demand for free access to color additive processes or formulae, whether any manufacturer will ever decline this, what the Commissoner would do if so refused, and what result a hearing would have. The fact that the Commissioner's proclamation of the possible consequences of refusal may induce manufacturers to be more compliant than if he had kept silent until an episode calling for action arose is not a sufficient basis for declaratory relief. Moreover, it is impossible to see what declaration a court could properly make. No one could reasonably assert that circumstances warranting suspension of certification if a manufacturer refused to give the FDA information concerning processes or formulae could never arise; Congress' failure to empower the agency to compel an inspection of processes of formulae is not a mandate to grant certificates when the public cannot properly be protected otherwise. Review of this Regulation should be on a case by case basis and with a factual record to assist in determining whether access to secret processes and formulae is necessary and appropriate to performance of the task of effective premarketing clearance in a particular instance—at least in the absence of experience showing consistent abusive tactics.

The judgment with respect to Count 4 is reversed with instructions to grant the motion to dismiss; the judgment with respect to Counts 1, 2, and 3 is affirmed, with further proceedings to be promptly taken in the district court in accordance with this opinion.

Appendix B

Judgment of the Court of Appeals For the Second Circuit

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Courthouse in the City of New York, on the thirteenth day of April one thousand nine hundred and sixty-six.

Present: Hon. Sterry R. Waterman, Hon. Leonard P. Moore, Hon. Henry J. Friendly, Circuit Judges.

The Toilet Goods Association, Inc., et al., plaintiffs-appellees,

v.

Anthony J. Celebrezze, Secretary of Health, Education and Welfare, and George P. Larrick, Commissioner of Food and Drugs, defendants-appellants

---

Appeal from the United States District Court for the Southern District of New York.

This cause came on to be heard on the transcript of record from the United States District Court for the Southern District of New York, and was argued by counsel.

ON CONSIDERATION WHEREOF, it is now hereby ordered, adjudged, and decreed that the order of said District Court be and it hereby is affirmed as to the First, Second and Third Counts of the complaint.

It is further ordered that the order of said District Court be and it hereby is reversed as to the Fourth Count of the complaint with instructions to grant the motion to dismiss in accordance with the opinion of this court.

A. DANIEL FUSARO,
Clerk.

APPENDIX C

1. The Federal Declaratory Judgment Act, 28 U.S.C. 2201, provides, in pertinent part:

> *Creation of remedy*
>
> In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. * * *

Section 10 of the Administrative Procedure Act, 60 Stat. 243, 5 U.S.C. 1009, provides in pertinent part:

> Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—
>
> (a) RIGHT OF REVIEW.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.
>
> (b) FORM AND VENUE OF ACTION.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial re-

view in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

(c) REVIEWABLE ACTS.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

Section 201(t)(1) of the 1960 "Drug Additive" amendments to the Federal Food, Drug and Cosmetic Act, 74 Stat. 397, 21 U.S.C. 321(t)(1) provides:

The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation,

determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

21 C.F.R. 8.1(f) provides in pertinent part:

> A "color additive" is any material, not exempted under section 201(t) of the act * * *. This includes all diluents. * * * A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are color additives. * * *

21 C.F.R. 8.1(m) provides:

> The term "diluent" means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve aother functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

21 C.F.R. 8.1(u) provides:

> The "hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives with the sensitization protential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious sub-

stance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.

21 C.F.R. 8.28(a)(4) provides:

(a) When it appears to the Commissioner that a person has:

* * * * *

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

U.S. GOVERNMENT PRINTING OFFICE: 1966

Also, similar questions of "ripeness" and "justiciability" are involved in *Abbott Laboratories* v. *Gardner*, in which this Court has granted certiorari, 383 U.S. 924, No. 39, this Term. In these circumstances, while we believe that the court of appeals rendered the correct decision on the question presented by the instant petition,[1] we agree that it would be appropriate either to defer consideration of this petition until after the decision in *Abbott Laboratories* v. *Gardner* or to grant this petition and our cross-petition so that the Court may consider the issues presented in the varying factual contexts.

Respectfully submitted.

THURGOOD MARSHALL,
Solicitor General.

AUGUST 1966.

---

[1] The challenged regulation provides that the Food and Drug Commissioner "may immediately suspend certification service" of a color additive when the manufacturer has "[r]efused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacturer of color additives and intermediates from which such color additives are derived" (21 C.F.R. 8.28(4)). The court of appeals held that review was premature since the regulation "simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification" (360 F. 2d at 687) and since a companion regulation (21 C.F.R. 8.28(b)) provides for an administrative hearing on the propriety of the withdrawal of certification. Review may presumably be had in the court of appeals if the commissioner were to insist upon withdrawing certification (Pet. App. A, pp. 1–21).

U.S. GOVERNMENT PRINTING OFFICE: 1966